



Healthcare
Improvement
Scotland

SMC
Advice on new
medicines

Guidance on Horizon Scanning Process

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1. Purpose of Document

The purpose of this guidance document is to give stakeholders, particularly the pharmaceutical industry, an overview of Scottish Medicines Consortium (SMC) horizon scanning processes and outputs, including standard documentation. The Association of the British Pharmaceutical Industry (ABPI) has contributed to the development and maintenance of these processes through the SMC User Group Forum.

The aims, processes, timelines and outputs of the horizon scanning initiative are described, with an emphasis on how pharmaceutical companies can optimise their contribution. The document also outlines the type and sources of information that are of value to SMC in providing NHS Boards with a realistic forecast of the potential budget impact of new medicines.

2. Background

In 2003 the Scottish Government requested that the SMC establish a horizon scanning initiative to provide Scottish NHS Boards with advance intelligence on new medicines.

The main focus of SMC horizon scanning is to provide financial planners with reliable information to support resource planning for the managed introduction of new medicines and new indications for existing medicines. Within NHS Scotland, Boards manage their own budgets, including managing funds for new medicines.

Provision of robust intelligence about medicines in the pipeline and their potential cost impact aims to facilitate patient access to cost-effective new medicines at the earliest opportunity after SMC approval. Horizon scanning intelligence also assists SMC in workload planning in relation to new medicine assessments.

Since 2005 SMC has produced an annual horizon scanning report, entitled *Forward Look*, to provide NHS Boards with information on potentially 'high impact' medicines.

A new medicine or indication is regarded as 'high impact' if it:

- has a predicted net medicine budget impact (relative to comparators) for NHSScotland of greater than £500,000 per annum or,
- may be associated with major service implications.

Forward Look provides information on new medicines or indications expected to reach the UK market between 1 July of the year the report is published and 30 June of the following year. It is assumed that these medicines will be accepted for use by SMC and based on internal analysis, on average will have an impact approximately nine months after the UK launch date (i.e. an impact in the following financial year).

SMC defines the launch date for a new medicine as the date when the medicine is expected to be in the UK supply chain (i.e. in the country). The launch date for a new indication of a medicine already marketed in the UK is the updated Medicines and Healthcare products Regulatory Agency (MHRA) marketing authorisation date for the licence extension.

3. Outputs

3.1 Forward Look Report

The key output is the annual *Forward Look* report issued in confidence each October to key Health Board personnel, including Chief Executive Officers and Directors of Medicine, Finance, Pharmacy and Public Health.

The *Forward Look* report is produced in spreadsheet format. This allows NHS Boards to modify factors (e.g. to adjust patient numbers for local epidemiology, to explore different rates of uptake based on local clinical expert opinion [see *section 6*], to search for new instances of a particular medicine, or to filter new indications by formulation to aid service planning). The *Forward Look* report comprises:

- **All medicines list spreadsheet** includes new medicines / indications, listed by British National Formulary (BNF) chapter, anticipated to have a UK launch within the timeframe of the report
- **Cancer medicines financial spreadsheet** provides information on net medicine budget impact for high impact medicines for cancer indications
- **Non-cancer medicines financial spreadsheet** provides information net medicine budget impact for high impact medicines for non-cancer indications

3.1.1 Financial spreadsheets (non-cancer and cancer)

The financial spreadsheets summarise the estimated uptake and incremental net medicine budget impact of each 'high impact' medicine by geographical area (West, East and North of Scotland) and by individual NHS Board.

The spreadsheets include data on the following:

- Net cost (estimated or list price) of treatment per patient per year or net cost (estimated or list price) per patient per course, considering offset cost of substituted medicines as appropriate. Non-recoverable VAT is added where hospital administration is assumed.
- Estimated eligible population and the estimated uptake figures for patient numbers in the East, West and North of Scotland and individual Boards in years 1 and at steady state (when uptake is assumed to have stabilised). Patient numbers for each of the geographical areas and Boards are calculated based on mid-year population estimates from the National Records of Scotland.
- Estimated total cost of each high impact medicine in year 1 and at year 2 or steady state (assumed to be the maximum financial cost) for East, West and North of Scotland and individual Board.
- Impact assumptions for each high impact medicine. These explain how the eligible population, uptake and cost of medicine were estimated and may also include additional information on predicted impact.

3.2 Forward Look Updates

Information on medicines in development can change. Three updates are produced annually, in January, June and October. These updates highlight any significant developments or a change in information on medicines included in the main *Forward Look* report.

The updates include:

- Details of additional new medicines anticipated to become available in the UK within the *Forward Look* report timeframe, identified by the horizon scanning team after the initial *Forward Look* report publication
- Updates on medicines where the regulatory timeframe has changed
- Information on medicines included in previous *Forward Look* reports where clinical development has since been delayed or discontinued

3.3 Advanced Therapy Medicinal Products (ATMP) Report

The annual ATMP report summarises new medicines or indications for ATMPs expected to launch within an extended timeline compared with the current *Forward Look* report. Only brief details of the ATMP are included. The report is intended to give summary information on ATMPs in the pipeline to aid with early service planning. ATMPs are also included in their relevant *Forward Look* reports as described above, allowing for more detailed service and financial planning.

3.4 Diagnostic Tests – Cancer Medicines Report

This report is produced every six months and supports service planning. It includes cancer medicines/new indications expected to require a diagnostic test, focussing on those requiring a new test, or for a broadened test population.

3.5 Ad Hoc Advice / Briefings

Horizon scanning intelligence may be used to answer *ad hoc* enquires from staff within NHSScotland. These can range from simple enquiries about an expected UK launch date of a new medicine, to requests for more complex information. In answering enquires SMC maintains the confidentiality of any information provided in confidence by the pharmaceutical industry and would not disclose sensitive UK launch or cost data provided in confidence.

Where the Horizon Scanning team identifies a group of medicines are in development which may have a significant service implication, a more detailed, *ad hoc* briefing may be prepared to alert NHS Boards in Scotland to the nature of this likely service requirement, an example includes the *ad hoc* Monoclonal antibodies for Alzheimer's disease briefing.

4. Horizon Scanning Processes

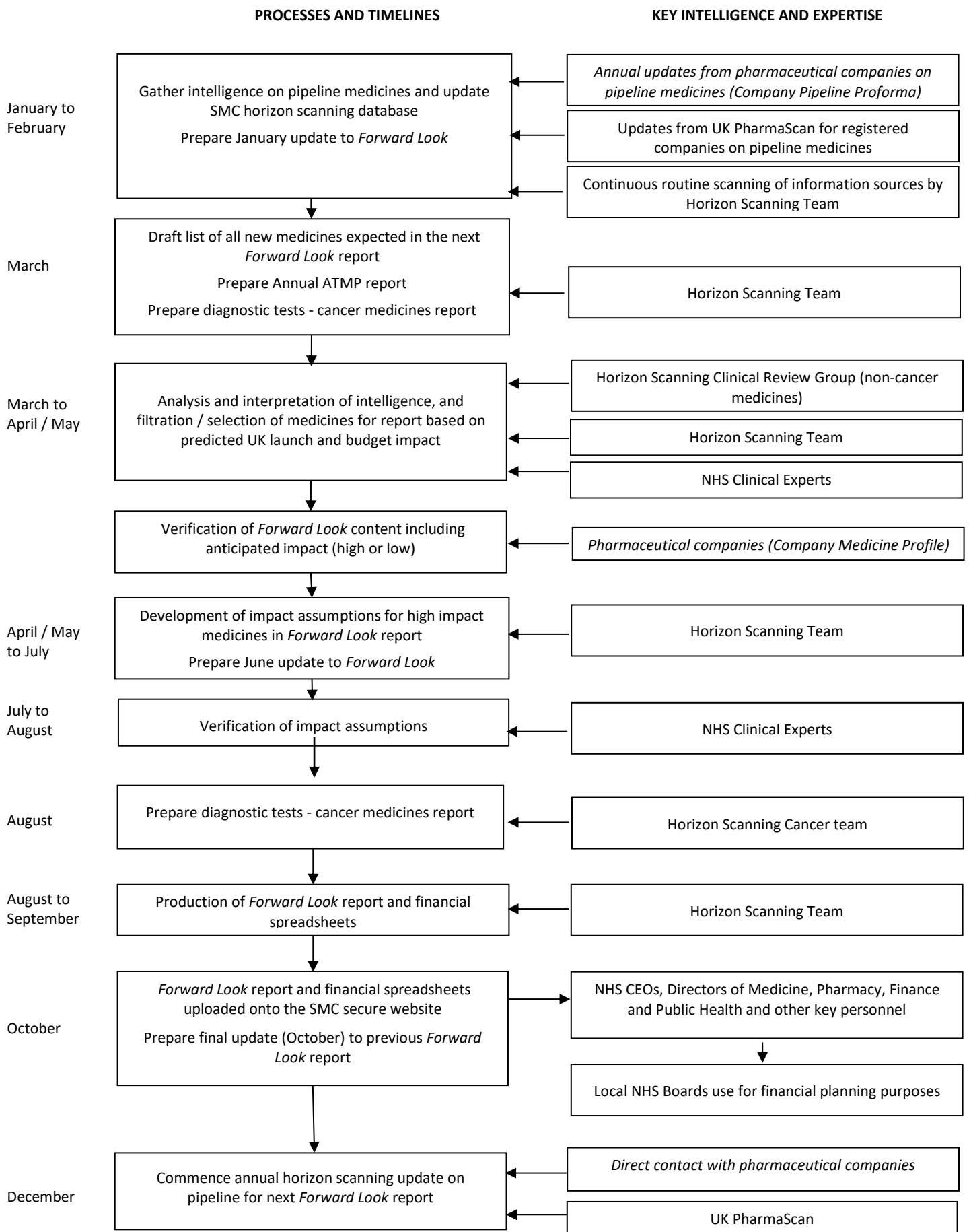
4.1 Overview and Timelines for *Forward Look*

Horizon scanning work is carried out by a team including pharmacists, health service researchers and a project officer, with finance support. Figure 1 provides an overview of horizon scanning processes and timelines.

The timelines for the production of the annual *Forward Look* report are driven by financial timelines in NHS Boards. In October each year planners require estimates of the potential budget and service impact of new medicines likely to be introduced in the following year. This informs decisions in annual budget setting processes. The horizon scanning team continually monitors this time difference to inform future adjustment to the *Forward Look* report timeframe.

Figure 1

SMC Horizon Scanning Production Process



4.2 Pharmaceutical Company Contacts

When a medicine in clinical development is identified and is expected to be included in the *Forward Look* report currently in development, the pharmaceutical company is identified. If SMC has not had any previous communication with the pharmaceutical company, the horizon scanning team will attempt to identify the most appropriate contact person within the organisation with responsibility for horizon scanning intelligence.

Companies planning to launch medicines in the UK that have not had previous engagement with SMC are requested to make contact to ensure that SMC is aware of their developments and is planning to include their medicines in future *Forward Look* publications. This allows for a streamlined introduction of new medicines into NHSScotland, should the medicine become licensed and accepted for use by SMC.

SMC maintains a database of named pharmaceutical company contacts. This includes details of the primary contact(s) in relation to both new product assessment process and the horizon scanning function. For some companies the same person may be responsible for both aspects of communication with SMC. Communication is routinely made by email. It is helpful if companies can advise SMC of any personnel or other changes to their contact details.

4.3 Collation of Intelligence

The horizon scanning team reviews a wide range of sources of information on new medicines in clinical development on an ongoing basis and maintains details of these within a confidential horizon scanning database. Sources include:

- UK PharmaScan (<https://www.ukpharmascan.org.uk>)
- Confidential NHS publications
- Public domain information from regulatory authorities, pharmaceutical and commercial analyst companies
- Other NHS organisations involved in horizon scanning work

SMC is committed to using UK PharmaScan as a key source of horizon scanning intelligence to produce our horizon scanning reports. UK PharmaScan is the primary source of information on new medicines, indications and formulations in the pharmaceutical pipeline and is used by all of the UK's national horizon scanning organisations and NHS England to plan and prepare the NHS for the introduction of new medicines and support faster NHS adoption. An information leaflet is available on the UK PharmaScan website at [Resources - UK Pharmascan](#) which provides further information and the market access processes across the UK. Information in UK PharmaScan can be invaluable if it is kept up to date and it is comprehensive. We would encourage all pharmaceutical companies to register with UK PharmaScan; please visit <https://www.ukpharmascan.org.uk/howtoregister>.

During production of a *Forward Look* report additional information and advice supporting the interpretation and application of horizon scanning data is obtained from a variety of sources, for example, epidemiological and prescription data from Public Health Scotland, as well as advice from clinical experts and pharmaceutical companies.

4.4 Pharmaceutical Company Intelligence

4.4.1 Pipeline updates from pharmaceutical companies

Pipeline updates are obtained by the SMC horizon scanning team via access to UK PharmaScan, or directly from the pharmaceutical company if it is not registered to use UK PharmaScan. If no UK PharmaScan record is available for a medicine/indication the pharmaceutical company will be asked to complete all data requested in a standard Company Pipeline Proforma issued by SMC in **December** each year (see [website](#) for the Company Pipeline Proforma, please note, the link is updated in December each year for the *Forward Look* report that will be published the following October). Note that information is requested for new medicines (new chemical entities), new indications, new formulations of existing medicines, biosimilars and ATMPs likely to be launched within the requested timeframe.

4.4.2 Company medicine profiles from pharmaceutical companies for *Forward Look*

Once the SMC horizon scanning team have collated the initial proposed list of medicines for the *Forward Look* report, they notify individual pharmaceutical companies by email around **April / May** detailing which medicines are planned to be included in the report. The communication specifies those medicines that are expected to have a high incremental net medicine budget impact (relative to comparators) or a significant service impact for NHS Scotland. Medicines considered to be high impact will require a company medicine profile to be completed by the pharmaceutical company (see [website](#) for company medicine profile; please note, the link is updated in May each year for the *Forward Look* report that will be published in the October of that year).

Pharmaceutical companies are asked to carefully consider the proposed content at this stage, particularly in relation to the estimated timelines for medicine availability in the UK and judgement about a medicine's potential for financial impact. Pharmaceutical companies should also inform the SMC horizon scanning team about any important omissions (i.e. medicines that SMC horizon scanning team has not identified for inclusion in the report should be highlighted).

Feedback from the pharmaceutical company at this stage is extremely helpful in ensuring that *Forward Look* features the relevant medicines and that the horizon scanning team's preliminary estimates of a medicine's anticipated incremental net medicine budget impact appear reasonable. Pharmaceutical companies that are registered with UK PharmaScan and whose records are complete and comprehensive will only be asked to complete a company medicine profile with additional information relevant to NHS Scotland.

SMC horizon scanning team acknowledges that pharmaceutical companies may have difficulty providing some of the requested information at this timepoint.

When pharmaceutical companies cannot provide a confirmed or anticipated medicine list price, estimates of uptake or duration of treatment, then best 'ballpark' range figures may be useful and can be provided with caveats. General advice about proposed costing strategies or estimated uptake can also be helpful. The table below contains examples of information that SMC would find useful in the absence of more precise estimates.

Information useful to SMC horizon scanning team	Examples
Acquisition cost An indication of potential cost range or upper or lower levels of range	<ul style="list-style-type: none"> Expected to cost between £5,000 to £10,000 per patient per annum Expected to cost more than £80,000 per patient per annum Expected to cost less than £500 per patient per annum
Cost relative to comparators An indication of potential cost relative to existing treatments	<ul style="list-style-type: none"> Will be priced in the same range as other drugs in class Likely to cost less than alternative treatments Likely to cost 10 % to 20 % more than alternative treatments
Estimated uptake An indication of uptake range or upper or lower levels of range	<ul style="list-style-type: none"> Likely to be given to at least 90 % of eligible population Likely to be given to less than 5 % of eligible population Likely to be given to between 40 % to 60 % of eligible population
Estimated uptake An indication of estimated uptake relative to existing treatments	<ul style="list-style-type: none"> Likely to replace existing drugs within the same class, but not increase numbers of patients prescribed this class Likely to be given to up to 10 % of patients already receiving this class of drug Likely to increase the proportion of the eligible population receiving drug therapy for this condition by up to 90 %

4.4.3 Ad hoc contact with pharmaceutical companies

Pharmaceutical companies may also be contacted on an *ad hoc* basis to clarify or provide additional information on particular medicines. Pharmaceutical companies are encouraged to contact SMC via email (his.smchorizonscanning@nhs.scot) at any time to update the information held about particular medicines, for example a change in the estimated UK launch date. Pharmaceutical companies registered to use UK PharmaScan should ensure that their product pipeline information is kept up to date on a regular basis and that changes to regulatory information are updated immediately the information becomes available to the pharmaceutical company.

4.5 Work Up of High Impact Medicines for *Forward Look*

Medicines considered to be potentially high impact for the *Forward Look* report are investigated in detail by the SMC horizon scanning team so that impact assumptions can be drafted. This includes undertaking a comprehensive literature search and considering relevant information from the pharmaceutical company (including the company medicine profile) as well as clinical experts.

Information is gathered on the following:

- How does the new product differ from existing products (e.g. pharmacology, route of administration)?
- What is the likely indication for the new product? Will it be a full or part trial population?
- How many people in Scotland would be eligible for treatment with the new product, and what proportion of the eligible population is likely to receive the new product?
- What is the incremental medicine acquisition cost of the new product relative to existing products?
- Would the new medicine be associated with any major service implications?

After identifying and assessing relevant available data, the impact assumptions are drafted and are peer reviewed within the SMC horizon scanning team.

4.6 Clinical Experts for *Forward Look*

A Clinical Review Group meeting is held in April each year to review non-cancer medicines. The purpose of this meeting is to identify non-cancer medicines that are likely to be low impact from the *Forward Look* draft list, in order that the horizon scanning team can focus on those medicines expected to be high impact.

Once the horizon scanning team has drafted impact assumptions for a high impact medicine, advice is sought in confidence from clinical experts from a number of NHS Boards across Scotland, where possible. SMC works closely with expert clinicians practising within NHSScotland and maintains a database of clinical expert contacts. For rare conditions, additional efforts may be made to identify further relevant clinical experts, for example via requests to Scottish Area Drug and Therapeutics Committees (ADTCs) or identification of relevant clinicians practising within the NHS in England, Wales or Northern Ireland.

Advice from clinical experts can be invaluable at this stage as they can provide specific intelligence from a Scottish perspective on current treatment options, current treatment protocols and guidelines, patients eligible for treatment with the condition being considered and likely uptake.

5. Confidentiality

The provision by the pharmaceutical industry of intelligence, that is often commercially sensitive, is central to the success of SMC's horizon scanning work. The risks to a pharmaceutical company associated with the release of this confidential information are comprehensively appreciated by SMC. SMC takes appropriate steps to safeguard the security of horizon scanning information provided by pharmaceutical companies. Horizon scanning intelligence is maintained in strict confidence and stored securely within the in-house horizon scanning database, accessible to SMC staff only.

Because of the commercial in confidence nature of the content, *Forward Look* reports and updates are accessed through a secure website. The secure website can only be accessed by key named individuals within NHSScotland, including Chief Executive Officers and Directors of Finance, Pharmacy, Medicine and Public Health. These NHS Board personal are made aware that information included within the *Forward Look* report is confidential and intended for those specifically authorised to access it for planning of resource and estimating budgets. In this regard NHSScotland personnel who have access to the *Forward Look* reports sign a confidentiality agreement each year that is accompanied by a code of practice on the appropriate use of the intelligence in the reports.

If NHS Boards receive requests under the Freedom of Information (FOI) Act relating to information within the reports it is strongly recommended that they consult with partners at SMC prior to the release of any information. If Boards, when using *Forward Look*, extract information from the report and incorporate into local documents, these must state the commercially sensitive nature of the information and the recommendation to refer any FOI requests relating to it to SMC.

When NHS clinicians are consulted for clinical expert input they agree to maintain the confidentiality of any information they receive in relation to their work for SMC. When these clinicians are approached to comment on draft impact assumptions, the confidential nature of the information is highlighted and the need to maintain the confidentiality of this information is reiterated.

6. Using the *Forward Look* Report in Practice

NHS Boards have established processes, mainly through ADTCs and prescribing advisory structures, to utilise the intelligence in the *Forward Look* report for financial and service planning purposes. The information in relation to specific high impact medicines is often shared in confidence with local clinical specialists or groups to seek their opinion on the estimates used in the *Forward Look* report. This may provide reassurance, for example, with regard to the estimated number of patients to be treated or may prompt some reworking of the figures to reflect local epidemiology, treatment of patients within clinical studies, or other aspects of how care is provided. After consideration has been given to the application of the *Forward Look* report in the Health Board (or region, for new cancer medicines), further internal reports may be prepared and provided to NHS Boards or regional advisory groups. If any part of the report is shared with individuals who are not named recipients of the report, they should be made aware of the confidentiality issues, and they will be asked to sign and return a confidentiality agreement to SMC.

SMC and NHS Boards recognise that the figures in the *Forward Look* report may represent a 'worst case scenario' given that some of the new medicines listed might not reach the UK market within the predicted timeframe or at all. Of those that do reach the UK market within the timeframe, a proportion will not be accepted by SMC for use in NHSScotland, and in these cases the predicted cost impact will not be realised. To account for this, NHS Boards may choose to apply a 'modifying factor' to generate a more realistic figure for the costs that may be realised in practice. There are inherent risks in this approach, as a result of uncertainty around what constitutes an appropriate figure, and NHS Boards understand the need to regularly review local projections to reflect SMC advice and its forthcoming work programme.

The *Forward Look* financial spreadsheets have been developed to allow this ongoing, dynamic in year adjustment by NHS Boards. For example, if a new medicine is considered by SMC but not recommended for use in Scotland, then the Board may remove it from their cost projections for the remainder of the current year. If the UK launch of a new medicine is delayed by approximately six months, then it is a straightforward step to adjust the projected costs accordingly.

Where SMC accepts a medicine for use or issues an ultra-orphan medicine assessment report (following initial assessment) a full budget impact template for the medicine (provided by the pharmaceutical company as part of their submission to SMC) will be distributed to NHS Boards together with the SMC advice on the product. This is to allow each Board to have access to a tool to assist with working out the implications of implementation of the product at a local level. If the advice on a product is 'not recommended' then the template will not be distributed to NHS Boards.

7. Summary

Publication of *Forward Look* and other horizon scanning outputs benefits from a close working with pharmaceutical companies to ensure effective, efficient communication to NHS Boards of new medicines in clinical development for their managed introduction to NHSScotland.

For further information or for any enquiries, please contact SMC horizon scanning at:
his.smchorizonscanning@nhs.scot.

Scottish Medicines Consortium
Healthcare Improvement Scotland

www.scottishmedicines.org.uk